

## **REMARKS**

### **I. STATUS OF THE CLAIMS**

Claims 1-53 were pending and subject to restriction. Claims 54-57 have been added. Support for new claims can be found in the claims as originally filed. Claims 1-57 are currently pending.

### **II. RESPONSE TO RESTRICTION REQUIREMENT**

#### **A. Group II Provisionally Elected**

In response to the Office Action mailed September 28, 2006 requiring restriction of the present claims, Applicants elect with traverse Group II (claims 42-45). Applicants respectfully traverse the restriction.

#### **B. Group I, II, III, IV, and VI**

The Action contends that Group I, II, III, IV, and VI are distinct, each from the others. The Action's position is that the inventions as claimed are not connected in at least one of design, operation, or effect and wherein at least one invention is patentable over the other. The Action alleges that the methods claimed are "distinct from one another because they recite different and distinct steps which lead to different and distinct products." The Action supports its position by stating that "the method of Group II invention does[sic] not have a step for lysis or use; the method of Group III invention does not have a step for lysis of cells" and that "the methods of Group I and Group IV invention have different concentration[s] of guanidinium and alcohol in the steps." Applicants traverse the restriction because the Action has not established a basis for asserting that the claims of Group I, II, III, IV, or VI present an undue burden on the Examiner.

The MPEP indicates that a restriction is proper if (1) the inventions are independent or distinct AND (2) there is a serious burden on the examiner. MPEP § 803. In addition, the MPEP states that a *prima facie* case of undue burden can be shown if the Examiner shows by appropriate explanation one of the following: (A) Separate classification, (B) A separate status in the art when they are classifiable together, and (C) A different field of search. Furthermore, the MPEP § 808.02 states:

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions. (emphasis added)

In this case, the Action does not establish that an undue burden exists. In particular, there has been no showing of separate classification and no clear indication of separate status in the art or of a different field of search. Examination of claims 1-48 and 50-57 is respectfully requested.

**1. All claim groups are class 536, subclass 25.4**

Each of the Groups (I-VI) are classified in class 536, subclass 25.4, therefore the subject matter of each group is not in a separate classification or sub-classification (page 2 of the Action).

**2. No showing of separate status in the art or undue burden**

The various limitations in the claims of Group I, II, III, IV, or VI do not establish that each Group has a separate status in the art. Furthermore, an undue burden is not imposed upon the Examiner in searching the similar elements of Groups I, II, III, IV, and VI. The Action provides little explanation in establishing the separate status of each claim grouping and in establishing an undue burden on the Examiner. In establishing the separate status of the claim groupings and the undue burden of searching all claims, the Action relies on the generic

statements on page 3 of the Action that read “The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. . .”. Such a conclusory statement does not provide an explanation as to why the particular claims at issue have a separate status in the art or would pose an undue burden on the Examiner.

Applicants position is that the claims of Groups I, II, III, IV, and VI are directed generally to the isolation of small RNA, which includes miRNA and siRNA, and contain similar steps for the isolation of small RNAs. For instance, claim 1 reads:

A method for isolating small RNA molecules from cells comprising:

- a) lysing the cells with a lysing solution to produce a lysate;
- b) adding an alcohol solution to the lysate;
- c) applying the lysate to a solid support;
- d) eluting small RNA molecules from the solid support; and,
- e) using or characterizing the small RNA molecules.

**Claim 42** of Group II contains steps similar to steps b, c, and e of claim 1. Claim 42 reads (steps similar to claim 1 in bold):

A method for isolating miRNA or siRNA from a sample comprising:

- a) obtaining a sample having miRNA or siRNA;
- b) adding an alcohol solution to the sample;**
- c) adding an extraction solution to the sample;
- d) applying the sample to a mineral or polymer support;**  
**and**
- e) eluting the siRNA or miRNA from the mineral or polymer support.**

Furthermore, step a of claim 42 is similar to dependent claim 2 (“ . . . wherein the small RNA molecules include miRNA, siRNA . . .”) and step c of claim 42 is similar to dependent claim 15

("... further comprising extracting small RNA molecules. . ."). Thus, a search of Group I would be coextensive with a search of Group II.

**Claim 46** of Group III contains steps similar to steps b, c, d, and e of claim 1. Claim 46 reads (steps similar to claim 1 in bold):

A method for isolating miRNA molecules from a sample comprising:

- a) **adding an alcohol solution to the sample;**
- b) **applying the sample to a mineral or polymer support;**
- c) **eluting miRNA molecules from the support; and**
- d) **using or characterizing the miRNA molecules.**

A search of Group I would be coextensive with a search of Group III.

**Claim 48** of Group IV contains steps similar to steps a, b, c, d, and e of claim 1. Claim 48 reads (steps similar to claim 1 in bold):

A method for isolating small RNA molecules from a sample comprising:

- a) **lysing cells in the sample with a lysing solution comprising guanidinium, wherein a lysate with a concentration of at least about 1 M guanidinium is produced;**
- b) **extracting small RNA molecules from the lysate with an extraction solution comprising phenol;**
- c) **adding to the lysate an alcohol solution for form a lysate/alcohol mixture, wherein the concentration of alcohol in the mixture is between about 35% to about 70%;**
- d) **applying the lysate/alcohol mixture to a mineral or polymer support;**
- e) **eluting the small RNA molecules from the mineral or polymer support;**
- f) **capturing the small RNA molecules; and**
- g) **using the isolated small RNA molecules.**

Furthermore, step b of claim 48 is similar to dependent claim 15 ("... further comprising extracting small RNA molecules. . .") and step f of claim 48 is similar to dependent claim 35 ("... further comprising capturing the eluted small RNA molecules."). Thus, a search of Group I would be coextensive with a search of Group IV.

**Claim 50** of Group VI contains steps similar to steps a, b, c, and d of claim 1. Claim 50 reads (steps similar to claim 1 in bold):

A method for isolating small RNA molecules from a sample comprising:

- a) **lysing cells in a lysing solution to produce a lysate;**
- b) extracting small RNA molecules from the lysate with an extraction solution comprising phenol;
- c) **adding to the lysate an alcohol solution to form a lysate/alcohol mixture;**
- d) **applying the lysate/alcohol mixture to a first solid support;**
- e) collecting flow-through lysate/alcohol mixture;
- f) **adding to the flow-through lysate/alcohol mixture an alcohol solution;**
- g) **applying the lysate/alcohol mixture to a second solid support; and**
- h) **eluting small RNA molecules from the solid support.**

Furthermore, step b of claim 50 is similar to dependent claim 16 (“... wherein the extraction solution comprises phenol. . .”). Thus, a search of Group I would be coextensive with a search of Group VI.

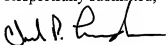
In traversing the Restriction Requirement on the grounds set forth above, Applicants specifically take no position with regard to whether any sets of the present claims or any individual present claims are or are not patentably distinct from any other set of claims or individual claim. Rather, Applicants argue without acquiescence that, under the circumstances of this case and in view of the applicable rules and statements of the MPEP, the stated restriction is not proper, whether those claims are patentably distinct or not. Such arguments do not create an estoppel against Applicants and are not an admission that the restricted Groups are either patentably distinct or patentably indistinct from one another.

In conclusion, each of the claim groupings are directed to similar and overlapping methods of varying scope, as demonstrated by claims dependent from, either directly or

indirectly, claim 1 of Group I. There must be a serious burden on the examiner (MPEP § 808.02). The Action does not establish an undue burden on the Examiner. For the reasons provided above, Applicants respectfully request the examination of all claims in Groups I, II, III, IV, and VI.

The Examiner is invited to contact the undersigned agent at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: November 28, 2006